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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
Purged RJN

60 8th Street, N.E.
Atlanta, Georgia 30309

January 13, 2000

VIA FEDERAL EXPRESS

Herman B. Styron, Co-owner
Quality Seafood
Highway 12
Cedar Island, NC 28520

Warning Letter
00-ATL-23

Dear Mr. Styron:

On August 9 & 10, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm located at Cedar Island, North Carolina. During that inspection, our investigator documented serious deviations from FDA's Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh shrimp and histamine-susceptible fish to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the appropriate monitoring procedures for each critical control point, in order to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for shrimp does not list the appropriate monitoring procedure associated with your critical limit, at an adequate frequency, at the receiving critical control point, to control sulfite use. Specifically, your plan does not state that you will monitor each lot of shrimp at receiving for a letter of guarantee from the vessel's captain certifying that no sulfites were used on the shrimp.

2. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrotoxin-forming species of fish does not list a specific maximum core temperature as a critical limit at the receiving critical control point to control histamine development.

3. You must have a HACCP plan that lists adequate monitoring procedures for each critical control point, in order to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for scombrotoxin-forming species of fish lists a monitoring frequency at the

receiving critical control point that is not adequate to control histamine development. Specifically, your plan does not state that the core temperature will be taken for each lot of fish at receiving, as well as a visual check for ice.

4. You must have a HACCP plan that lists adequate critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrotoxin-forming species of fish does not provide an adequate temperature as the critical limit at the "cooler storage" critical control point to control histamine development. Specifically, a temperature of 45 degrees F for cooler storage is inadequate for controlling histamine development. The *Fish and Fisheries Products Hazards & Control Guide* (Chapter 7, Scombrotoxin (Histamine) Formation) recommends that products not exceed 40 degrees F for more than 4 hours, cumulatively.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Ballard H. Graham, Director
Atlanta District